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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,094	10/21/2005	Katsuyoshi Nagao	06854.0046	6586

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EXAMINER

MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,094

Applicant(s)

NAGAO ET AL.

Examiner

Adam Marcetich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 21 Oct 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. PCT/JP/2004/005547, filed on 19 April 2004 has been received.

Information Disclosure Statement

2. The information disclosure statement filed 19 January 2006 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract is objected to for exceeding a length of 150 words.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1,4-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US Patent 4,502,616) in view of Komatsu et al. (US Patent 3,892,058).

8. Regarding claim 1, Meierhoefer discloses an ampoule comprising:
a flexible container body (column 3, lines 56-65 and Fig. 3, vials or ampoules 12);
a fusion-bonded portion which seals a mouth of the container body (column 4, lines 25-36 and Fig. 3, seal 44); and
a holder tab connected to the fusion-bonded portion for wrenching off the fusion-bonded portion (column 4, lines 25-36 and Fig. 3, key 26).

The ampoule of Meierhoefer comprises plastic (column 3, lines 56-65), therefore it naturally follows that it is capable of preventing drug permeation.

Meierhoefer lacks a container body including two or more layers. Komatsu discloses a container including two or more layers (column 6, lines 23-33 and Fig. 1, layers 1-3). Komatsu solves the problem of providing sterile packaging (column 1, lines 5-10). Komatsu provides the advantage of providing better heat distribution during sterilization by using a metal foil layer (column 2, lines 25-34, 44-50, column 6, lines 23-33 and Fig. 1, inner layer 2 composed of metal foil).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ampoule of Meierhoefer with the metal foil of Komatsu in order to provide better heat distribution during a sterilization process.

9. Regarding claim 4, Meierhoefer in view of Komatsu discloses the invention as substantially claimed. See above. However, Meierhoefer lacks a functional layer being a

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polyamide layer. Komatsu discloses a polyamide layer (column 6, lines 23-33 and Fig. 1, inner layer 1). Komatsu provides the advantage of a heat-sealable material that allows heat sealing during manufacture while allowing heat sterilization (column 7, lines 14-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ampoule of Meierhoefer with the polyamide of Komatsu in order to provide both heat sealing and heat sterilization capabilities as taught by Komatsu.

10. Regarding claims 5 and 6, Meierhoefer is silent with respect to the material used to form ampoule 12. Komatsu discloses an ampoule comprising a polyester layer (column 6, lines 23-33, and Fig. 1, outer layer 3 comprising polyester). Komatsu provides the advantage of providing a heat resistant layer, which is needed during heat sterilization. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ampoule of Meierhoefer with the polyester of Komatsu in order to provide a heat sterilizable container. It naturally follows that polyester is a polyol (online encyclopedia, "Polyol").

11. Regarding claim 12, Meierhoefer discloses an ampoule having a volume of 0.5 to 20mL (column 4, lines 7-9). Meierhoefer lacks a functional layer as claimed. Komatsu discloses a functional layer having a steam permeation preventing capability and drug absorption/adsorption preventing capability (column 6, lines 23-33 and Fig. 1, layers 1-3). It naturally follows that a foil layer is capable of preventing steam permeation capability and preventing drug absorption/adsorption. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

the ampoule of Meierhoefer with the metal foil of Komatsu in order to provide better heat distribution during a sterilization process.

12. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US Patent 4,502,616) in view of Komatsu et al. (US Patent 3,892,058) in view of Takanashi et al. (US Patent 4,537,305).

13. Regarding claim 2, Meierhoefer in view of Komatsu discloses the invention substantially as claimed. See above. However, Meierhoefer in view of Komatsu lacks an innermost layer composed of a resin comprising a polyolefin or a polycycloolefin. Takanashi discloses a container having an innermost layer composed of a resin comprising a polyolefin (column 3, lines 4-14 and Fig. 2, inner polyolefin layer 3). Takanashi solves the problem of forming a medical storage container (column 1, lines 9-14). Takanashi provides the advantage of a thermally resistant polymer (column 3, lines 27-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Komatsu as discussed with the polyolefin of Takanashi in order to provide thermally resistant polymer during a sterilization process.

14. Regarding claim 3, Meierhoefer in view of Komatsu lacks an additive as claimed. Takanashi discloses a layer provided as other than an innermost layer and composed of a material containing an oxygen absorbing agent (column 4, lines 51-55 and Fig. 2, deoxidizer 13). Takanashi provides the advantage of absorbing oxygen, to prevent degradation of a medical solution (column 1, lines 39-43). Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Komatsu as discussed with the oxygen absorbing agent of Takanashi in order to prevent degradation of a medical solution as taught by Takanashi.

15. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US Patent 4,502,616) in view of Komatsu et al. (US Patent 3,892,058) in view of Itoh et al. (US Patent 6,042,906).

16. Regarding claim 7, Meierhoefer in view of Komatsu discloses the invention substantially as claimed. See above. However, Meierhoefer in view of Komatsu lacks a polycycloolefin. Itoh discloses a container comprising a polycycloolefin layer (column 6, lines 40-47 and Fig. 3, intermediate layer 12 comprising cyclic olefin copolymer). Itoh solves the problem of providing an impermeable container (column 1, lines 6-13). Itoh provides the advantage of low moisture permeability (column 1, lines 39-48). Itoh further provides the advantage of retaining flavors, therefore it naturally follows that a polycycloolefin is resistant to movement of volatile substances that may be contained within a medical container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Komatsu as discussed with the polycycloolefin of Itoh in order to provide low moisture permeability as taught by Itoh, and additionally resist movement of volatile substances.

17. Regarding claims 8 and 9, Meierhoefer in view of Komatsu discloses the invention substantially as claimed. See above. However, Meierhoefer in view of Komatsu lacks a polycycloolefin. Itoh discloses a container comprising a polycycloolefin layer as discussed for claim 7 above. Itoh further discloses a polycycloolefin having a glass transition temperature overlapping the claimed ranges (column 14, lines 57-61). Itoh discloses excellent barrier properties of a cyclic olefin having a glass transition temperature overlapping the claimed ranges (column 7, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Komatsu as discussed with the polycycloolefin of Itoh in order to provide excellent barrier properties as taught by Itoh.

18. Regarding claim 10, Meierhoefer in view of Komatsu lack a polycycloolefin. Itoh discloses a container comprising a polycycloolefin layer as discussed for claim 7 above. Itoh further discloses a pair of layers comprising polycycloolefin (column 6, lines 48-57 and Fig. 4, first intermediate layer 22 and third intermediate layer 24). Itoh discloses excellent barrier properties of a cyclic olefin having a glass transition temperature overlapping the claimed ranges (column 7, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Meierhoefer in view of Komatsu as discussed with the polycycloolefin of Itoh in order to provide excellent barrier properties as taught by Itoh.

19. Regarding claim 11, Meierhoefer discloses an ampoule sequence including a plurality of ampoules connected to one another via severable thin wall portions (column 4, lines 45-49 and Fig. 1, separation strip 36).

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US Patent 6,254,376) in view of Komatsu et al. (US Patent 3,892,058).

21. Regarding claim 13, Louviere discloses a production method for a drug solution filling plastic ampoule comprising the steps of:

molding a container body by holding a tubular parison between lower split mold pieces (column 5, lines 57-62 and Fig. 1, core pins 68, 70 and slide inserts 26, 28; column 9, lines 47-65). Louviere discloses forming a hollow plastic article (column 9, lines 31-34) therefore it naturally follows that that Louviere has a step of forming a void in a parison.

A parison is defined as a partially shaped mass of molten glass (online dictionary, "parison"). Applicant has not further defined the term "parison" in the specification, therefore it is given its plain meaning. Liquidized plastic reasonably meets the definition of "parison" in the context of plastic molding.

Louviere discloses a step of filling a drug solution in a container body (column 10, lines 28-37).

Louviere substantially discloses holding a mouth of a container body between upper split mold pieces to form a fusion-bonded portion which seals the mouth of the container body and a holder tab which is connected to the fusion-bonded portion to be used for wrenching off the fusion-bonded portion (column 9, lines 34-41 and Fig. 8, rectangular extension top 240A and nearby neck).

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Louviere discloses the invention substantially as claimed. However, Louviere lacks a parison having at least two layers. Komatsu discloses a container including two or more layers (column 6, lines 23-33 and Fig. 1, layers 1-3). Therefore, it naturally follows that Komatsu has a parison having at least two layers. Komatsu solves the problem of providing sterile packaging (column 1, lines 5-10). Komatsu provides the advantage of providing better heat distribution during sterilization by using a metal foil layer (column 2, lines 25-34, 44-50, column 6, lines 23-33 and Fig. 1, inner layer 2 composed of metal foil). The metal foil of Komatsu is substantially capable of preventing light ray permeation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ampoule of Louviere with the metal foil of Komatsu in order to provide better heat distribution during a sterilization process.

22. Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US Patent 6,254,376) in view of Komatsu et al. (US Patent 3,892,058) in view of Itoh et al. (US Patent 6,042,906).

23. Regarding claim 14, Louviere in view of Komatsu discloses the invention substantially as claimed. However, Louviere in view of Komatsu lacks a polyolefin or a polycycloolefin as claimed [claim 14]. Itoh discloses a container wherein an innermost layer is composed of a resin comprising a polyolefin (column 6, lines 40-47 and Fig. 3, intermediate layer 12 made of cyclic olefin resin). Examiner is interpreting the term "innermost" broadly, to include a layer within a container wall.

Itoh solves the problem of providing an impermeable container (column 1, lines 6-13). Itoh provides the advantage of low moisture permeability (column 1, lines 39-48). Itoh further provides the advantage of retaining flavors, therefore it naturally follows that a polycycloolefin is resistant to movement of volatile substances that may be contained within a medical container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere in view of Komatsu as discussed with the polycycloolefin of Itoh in order to provide low moisture permeability as taught by Itoh, and additionally resist movement of volatile substances.

24. Regarding claims 16 and 17, Louviere discloses the invention substantially as claimed. However, Louviere lacks a polycycloolefin as claimed [claims 16 and 17]. Itoh discloses a polycycloolefin and provides the advantage of resisting movement of volatile substances that may be contained within a medical container. Itoh further discloses a polycycloolefin having a glass transition temperature overlapping the claimed ranges (column 14, lines 57-61). Itoh discloses excellent barrier properties of a cyclic olefin having a glass transition temperature overlapping the claimed ranges (column 7, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere as discussed with the polycycloolefin of Itoh in order to provide excellent barrier properties as taught by Itoh.

25. Regarding claim 18, Louviere discloses the invention substantially as claimed. However, Louviere lacks polycycloolefin layers as claimed [claim 18]. Itoh further discloses a pair of layers comprising polycycloolefin (column 6, lines 48-57 and Fig. 4,

first intermediate layer 22 and third intermediate layer 24). Itoh discloses excellent barrier properties of a cyclic olefin having a glass transition temperature overlapping the claimed ranges (column 7, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere as discussed with the polycycloolefin of Itoh in order to provide excellent barrier properties as taught by Itoh.

26. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US Patent 6,254,376) in view of Komatsu et al. (US Patent 3,892,058) in view of Takanashi et al. (US Patent 4,537,305).

27. Regarding claim 15, Louviere in view of Komatsu disclose the invention substantially as claimed. However, Louviere in view of Komatsu lack an additive as claimed [claim 15]. Takanashi discloses a layer provided as other than an innermost layer and containing an oxygen absorbing agent (column 4, lines 51-55 and Fig. 2, deoxidizer 13). Takanashi provides the advantage of absorbing oxygen, to prevent degradation of a medical solution (column 1, lines 39-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Louviere in view of Komatsu as discussed with the oxygen absorbing agent of Takanashi in order to prevent degradation of a medical solution as taught by Takanashi. The metal foil layer of Komatsu as discussed is capable of being provided inward of the layer of the oxygen absorbing agent of Takanashi and preventing drug permeation.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Federighi (US Patent 4,512,475), Single or multiple dose container-closure assemblies.
- ❖ Newell (US Design Patent D289,200 S), Dose container.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761



AMM



LOAN H. THANH
PRIMARY EXAMINER